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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,826	12/02/2003	JeanThierry Simonnet	241891US0CONT	2739
22850 7590 03/29/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HUYNH, CARLIC K	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		03/29/2007	ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/29/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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**Office Action Summary**

Application No.

10/724,826

Applicant(s)

SIMONNET ET AL.

Examiner

Carlic K. Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-53 is/are pending in the application.
- 4a) Of the above claim(s) 44-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/460,092.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u>                                    | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :02 December 2003 and 16 July 2004.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 25-53 are pending in the application, with claims 44-53 having been withdrawn from consideration, in response to the restriction requirement submitted on December 1, 2006. Claims 1-24 have been cancelled in a Preliminary Amendment filed on December 2, 2003. Accordingly, claims 25-43 are being examined on the merits herein.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group I, namely claims 25-43, in the reply filed on December 27, 2006 is acknowledged. The traversal is on the ground(s) that the search for the system of Group I would uncover the method of Group II. This is not found persuasive because many products can be used with the process of Group II and thus the search for the products of Group I will not necessarily yield the process of Group II. Furthermore, if the product claims of Group I are found allowable, then the process claims of Group II will be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, as per *In re Ochiai*.

Claims 44-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made with traverse in the reply filed on December 27, 2006.

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3. Applicant's election with traverse of the species of (1) glucose esters (surfactant); (2) disodium salt of N-stearoyl-L-glutamic acid (amphiphilic lipid); and (3) isocetyl stearate (oil), in the reply filed on December 27, 2006 is acknowledged. The traversal is on the ground(s) that: (1) there are no details or examples to support surfactants, amphiphilic lipids and oils as being patentably distinct species; and (2) the species are related by operation and/or effect.

Applicants' arguments were found persuasive and the election of species requirement for (1) a surfactant, (2) an amphiphilic lipid, and (3) an oil is hereby withdrawn.

The restriction requirement, however, is still deemed proper and is therefore made FINAL.

#### ***Information Disclosure Statement***

The Information Disclosure Statement submitted on December 2, 2003 and July 16, 2004 is acknowledged.

#### ***Oath/Declaration***

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it does not identify the citizenship of each inventor. The citizenship of each inventor is listed as "French". French is not a proper country. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 25-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (U.S. Patent 5,753,241) in view of Ribier et al. (U.S. Patent 5,658,575), Matsumoto et al. (5,011,922), Valdivia et al. (U.S. Patent 5,698,219), and Nguyen et al. (6,669,849).

Ribier et al. (5,753,241) teach an oil-in-water nanoemulsion, in which the oil globules are less than 100 nm, and contain an amphiphilic lipid component (abstract). The amount of oil ranges from 5 to 30% by weight with respect to the total weight of the emulsion (column 3, lines 16-18). The oil can be a silicone oil, namely decamethylcyclopentasiloxane, which has a molecular weight of 370.78 (column 3, line 47). The oil can also be Jojoba oil, which contains 36 to 46 carbons, and has a molecular weight of at least 432 (column 5, example 1; and wikipedia.org). Jojoba oil makes up 50% of the oils having a molecular weight greater than 400 (column 5, example 1).

Furthermore, Ribier et al. (5,753,241) teach ionic amphiphilic lipids in the nanoemulsions, which can be alkaline salts of dicetyl and dimyristyl phosphate, alkaline salts of cholesterol sulphate, alkaline salts of cholesterol phosphate, sodium salts of phosphatidic acid, phospholipids, or alkylsulfonic derivatives (columns 2, lines 57-65; and column 3, lines 1-3). The ionic amphiphilic lipids are from 2 to 10% by weight (column 3, line 13).

Ribier et al. (5,753,241) also teach emulsions that contain additives to improve the transparency of the formulation, such as lower alcohols and are 5 to 20% by weight (column 3, lines 49-51, 53, and 62).

Ribier et al. (5,753,241) also teach the nanoemulsion for topical use such as a cosmetic or dermatopharmaceutical composition (column 4, lines 45-47).

Ribier et al. (5,753,241) do not teach nanoemulsions containing surfactants, nanoemulsions for ophthalmic use, or the turbidity of the nanoemulsion.

Ribier et al. (5,658,575) teach oil-in-water type emulsions with surfactants such as sucrose distearate (column 3, lines 42-43). The surfactant is 2 to 6% by weight of the emulsion (column 4, lines 2-3). The weight ratio of the oil to surfactant is from 2 to 13 (column 4, lines 15-17).

Matsumoto et al. teach sucrose distearate has a melting point of 110°C and temperatures lower than the melting point would be required for solidification of sucrose distearate (column 3, lines 33-34 and 50). Thus, the surfactant, which is sucrose distearate, in the instant application is reasonably expected to be a solid at temperatures equal to or less than 45°C as recited in instant claim 25.

Valdivia et al. teach a pharmaceutical vehicle that is a nanoemulsion and that the vehicle is especially useful in ophthalmic preparations (abstract).

Nguyen et al. teach a process for the removal of dissolved organic carbon from water (abstract). The organic carbon compounds in various water samples were coagulated, by addition of a coagulant, to form a floc, which can then be physically removed (column 1, lines 29-32). The turbidity of water samples where the floc size is 1-2 mm is 3.6 NTU (column 13,

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Table 2). Thus, the nanoemulsions of less than 100nm in the instant application are reasonably expected to have a turbidity measurement of 60 to 600 NTU as recited in instant claim 26.

To a person of skill in the art at the time of the invention, it would have been obvious to employ the nanoemulsions of Ribier et al. (5,753,241) to contain a solid surfactant because the compounds of Ribier et al. (5,658,575) are nanoemulsions and the compounds of Matsumoto et al. are the surfactant sucrose distearte and according to Matsumoto et al., the melting point of sucrose distearate is 110<sup>0</sup>C and at 45<sup>0</sup>C, sucrose distearate is reasonably expected to be a solid.

The motivation to combine the compounds of Ribier et al. (5,753,241) to the compounds of Ribier et al. (5,658,575) and Matsumoto et al. is that the compounds of Ribier et al. (5,658,575) are nanoemulsion compositions containing a nonionic surfactant and the compounds of Matsumoto et al. are a solid nonionic surfactant, sucrose distearate, at 45<sup>0</sup>C.

To a person of skill in the art at the time of the invention, it would have been obvious to employ the nanoemulsions of Ribier et al. (5,753,241) to have an ophthalmic use because the compounds of Valdivia et al. are pharmaceutical vehicles which are nanoemulsions and that the vehicles are useful in ophthalmic preparations and according to Valdivia et al., nanoemulsions can be used as an ophthalmic vehicle.

The motivation to combine the compounds of Ribier et al. (5,753,241) to the compounds of Valdivia et al. is that the compounds of Valdivia et al. are pharmaceutical vehicles and that such pharmaceutical vehicles, which are nanoemulsions, are useful in ophthalmic preparations.

To a person of skill in the art at the time of the invention, it would have been obvious to employ the nanoemulsions of Ribier et al. (5,753,241) to have a turbidity of 60-600 NTU because the compounds of Nguyen et al. are coagulated organic carbon compounds in water



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samples and according to Nguyen et al., coagulated organic carbon compounds in water have a turbidity of less than 60-600 NTU.

The motivation to combine the compounds of Ribier et al. (5,753,241) to the compounds of Nguyen et al. is that the compounds of Ribier et al. (5,753,241) are nanoemulsion compositions and the compounds of Nguyen are coagulated organic carbon compounds in water and that such compounds have a turbidity of 60-600 NTU.

### ***Double Patenting***

#### **Obviousness-Type**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 25 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-30 of Ribier et al. (U.S. Patent 5,658,575), claims 22-23 of Ribier et al. (U.S. Patent 5,753,241), claims 33 and 38-39 of Cervantes et al. (U.S. Patent

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5,925,341), claim 26 of Ribier et al. (U.S. Patent 6,066,328), claims 24-26 of Simonnet (U.S. Patent 6,120,778), claims 16-17 of Simonnet et al. (U.S. Patent 6,126,948), claims 20-23 of Simonnet (U.S. Patent 6,274,150), claims 20-23 of Simonnet et al. (U.S. Patent 6,335,022), claims 17-20 of Simonnet et al. (U.S. Patent 6,375,960), claims 22-26 of Simonnet et al. (U.S. Patent 6,413,527), claims 32-35 and 38 of Sonnevile et al. (U.S. Patent 6,419,946), claims 19-20 and 22-24 of Simonnet et al. (U.S. Patent 6,461,625), claims 20-25 of Simonnet et al. (U.S. Patent 6,464,990), claims 20-23 and 43-46 of Simonnet et al. (U.S. Patent 6,541,018), claims 42, 44, and 46 of Verite et al. (U.S. Patent 6,562,356), and claims 22-27 of L'Alloret et al. (U.S. Patent 6,998,426). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 29-30 of Ribier et al. (U.S. Patent 5,658,575), claims 22-23 of Ribier et al. (U.S. Patent 5,753,241), claims 33 and 38-39 of Cervantes et al., claim 26 of Ribier et al. (U.S. Patent 6,066,328), claims 24-26 of Simonnet (U.S. Patent 6,120,778), claims 16-17 of Simonnet et al. (U.S. Patent 6,126,948), claims 20-23 of Simonnet (U.S. Patent 6,274,150), claims 20-23 of Simonnet et al. (U.S. Patent 6,335,022), claims 17-20 of Simonnet et al. (U.S. Patent 6,375,960), claims 22-26 of Simonnet et al. (U.S. Patent 6,413,527), claims 32-35 and 38 of Sonnevile et al., claims 19-20 and 22-24 of Simonnet et al. (U.S. Patent 6,461,625), claims 20-25 of Simonnet et al. (U.S. Patent 6,464,990), claims 20-23 and 43-46 of Simonnet et al. (U.S. Patent 6,541,018), claims 42, 44, and 46 of Verite et al., and claims 22-27 of L'Alloret et al. are directed at a method of using or a method of making a nanoemulsion, which is the same nanoemulsion used in the instant claim 25. Thus the nanoemulsion is not patentably distinct between Ribier et al. (U.S. Patent 5,658,575), Ribier et al. (U.S. Patent 5,753,241), Cervantes et al., Ribier et al. (U.S. Patent 6,066,328), Simonnet (U.S. Patent

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6,120,778), Simonnet et al. (U.S. Patent 6,126,948), Simonnet (U.S. Patent 6,274,150), Simonnet et al. (U.S. Patent 6,335,022), Simonnet et al. (U.S. Patent 6,375,960), Simonnet et al. (U.S. Patent 6,413,527), Sonnevile et al., Simonnet et al. (U.S. Patent 6,461,625), Simonnet et al. (U.S. Patent 6,464,990), Simonnet et al. (U.S. Patent 6,541,018), Verite et al., L'Alloret et al., and the instant application.

7. Claim 25 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52-54 of copending Application Simonnet et al. (U.S. Patent Application No. 2004/0009131), claims 45 and 47 of copending Application Simonnet (U.S. Patent Application No. 2004/0258644), claims 75, 77, and 79 of copending Application Douin et al. (U.S. Patent Application No. 2005/0226842), claims 23-28 of copending Application L'Alloret et al. (U.S. Patent Application No. 2006/0030655), and claim 26 of copending Application Tank et al. (U.S. Patent Application No. 2007/0027034). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 52-54 of copending Application Simonnet et al. (U.S. Patent Application No. 2004/0009131), claims 45 and 47 of copending Application Simonnet (U.S. Patent Application No. 2004/0258644), claims 75, 77, and 79 of copending Application Douin et al., claims 23-28 of copending Application L'Alloret et al., and claim 26 of copending Application Tank et al. are directed at a method of using or a method of making of a nanoemulsion, which is the same nanoemulsion used in the instant claim 25. Thus the nanoemulsion is not patentably distinct between Simonnet et al. (U.S. Patent Application No. 2004/0009131), Simonnet (U.S. Patent Application No. 2004/0258644), Douin et al., L'Alloret et al., Tank et al., and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

8. Claim 25 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of Ribier et al. (U.S. Patent 5,658,575) and claim 1 of Ribier et al. (U.S. Patent 5,753,241), claim 1 of Cervantes et al. (U.S. Patent 5,925,341), claim 1 of Ribier et al. (U.S. Patent 5,925,364), claims 1 and 30 of Ribier (U.S. Patent 6,066,328), claim 1 of Simonnet (U.S. Patent 6,120,778), claim 1 of Simonnet et al. (U.S. Patent 6,126,948), claim 1 of Simonnet (U.S. Patent 6,274,150), claim 1 of Simonnet et al. (U.S. Patent 6,335,022), claim 1 of Simonnet et al. (U.S. Patent 6,375,960), claim 1 of Simonnet et al. (U.S. Patent 6,413,527), claim 1 of Sonnevile et al. (U.S. Patent 6,419,946), claim 1 of Simonnet et al. (U.S. Patent 6,461,625), claim 1 of Simonnet et al. (U.S. Patent 6,464,990), claims 1, 25, 42, and 48 of Simonnet et al. (U.S. Patent 6,541,018), claims 1, 33, 38-41, and 47 of Verite et al. (U.S. Patent 6,562,356), and claim 1 of L'Alloret et al. (U.S. Patent 6,998,426) in view of Ribier et al. (U.S. Patent 5,753,241), Ribier et al. (U.S. Patent 5,658,575), Matsumoto et al. (5,011,922), Valdivia et al. (U.S. Patent 5,698,219), and Nguyen et al. (6,669,849) as applied to claims 25-43 above.

9. Claim 25 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, and 20-22 of copending Application Sonnevile-Aubrun et al. (U.S. Patent Application 2003/0206955), claims 1 and 55 of copending Application Simonnet et al. (U.S. Patent Application No. 2004/0009131), claim 1 of copending Application Simonnet (U.S. Patent Application No. 2004/0258644), claims 1, 70-74, and 80 of copending Application Douin et al. (U.S. Patent Application No. 2005/0226842), claim 1 of copending Application L'Alloret et al. (U.S. Patent Application No. 2006/0030655), claim 1 of copending

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Application Simonnet (U.S. Patent Application No. 2006/0193813), and claims 1 and 30 of copending Application Tank et al. (U.S. Patent Application 2007/0027034) in view of Ribier et al. (U.S. Patent 5,753,241), Ribier et al. (U.S. Patent 5,658,575), Matsumoto et al. (5,011,922), Valdivia et al. (U.S. Patent 5,698,219), and Nguyen et al. (6,669,849) as applied to claims 25-43 above.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

### *Conclusion*

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

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